



## ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPP-2013-0230; FRL-9384-1]

### FIFRA Scientific Advisory Panel; Notice of Public Meeting

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

**SUMMARY:** There will be a 4-day meeting of the Federal Insecticide, Fungicide, and Rodenticide Act Scientific Advisory Panel (FIFRA SAP) to consider and review Weight-of-Evidence: Evaluating Results of EDSP Tier 1 Screening.

**DATES:** The meeting will be held July 30, 2013--August 2, 2013, from approximately 8:30 a.m. to 5 p.m.

*Comments.* The Agency encourages that written comments be submitted by July 16, 2013, and requests for oral comments be submitted by July 23, 2013. However, written comments and requests to make oral comments may be submitted until the date of the meeting, but anyone submitting written comments after July 16, 2013, should contact the Designated Federal Official (DFO) listed under **FOR FURTHER INFORMATION CONTACT**. For additional instructions, see Unit I.C. of the **SUPPLEMENTARY INFORMATION**.

*Nominations.* Nominations of candidates to serve as ad hoc members of FIFRA SAP for this meeting should be provided on or before [insert date 15 days from date of publication in the **Federal Register**].

*Webcast.* This meeting may be webcast. Please refer to the FIFRA SAP's website at <http://www.epa.gov/scipoly/sap> for information on how to access the webcast. Please note that the webcast is a supplementary public process provided only for

convenience. If difficulties arise resulting in webcasting outages, the meeting will continue as planned.

*Special accommodations.* For information on access or services for individuals with disabilities, and to request accommodation of a disability, please contact the DFO listed under **FOR FURTHER INFORMATION CONTACT** at least 10 days prior to the meeting to give EPA as much time as possible to process your request.

**ADDRESSES:** The meeting will be held at the Environmental Protection Agency, Conference Center, Lobby Level, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA 22202.

*Comments.* Submit your comments, identified by docket identification (ID) number EPA-HQ-OPP-2013-0230, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at

<http://www.epa.gov/dockets/contacts.html>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

If your comments contain any information that you consider to be CBI or otherwise protected, please contact the DFO listed under **FOR FURTHER INFORMATION CONTACT** to obtain special instructions before submitting your comments.

*Nominations, requests to present oral comments, and requests for special accommodations.* Submit nominations to serve as ad hoc members of FIFRA SAP, requests for special seating accommodations, or requests to present oral comments to the DFO listed under **FOR FURTHER INFORMATION CONTACT**.

**FOR FURTHER INFORMATION CONTACT:** Joseph E. Bailey, DFO, Office of Science Coordination and Policy (7201M), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-2045; fax number: (202) 564-8382; email address: *bailey.joseph@epa.gov*.

## **SUPPLEMENTARY INFORMATION:**

### **I. General Information**

#### *A. Does this Action Apply to Me?*

This action is directed to the public in general. This action may, however, be of interest to persons who are or may be required to conduct testing of chemical substances under the Federal Food, Drug, and Cosmetic Act (FFDCA) and FIFRA. Since other entities may also be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action.

#### *B. What Should I Consider as I Prepare My Comments for EPA?*

When submitting comments, remember to:

1. Identify the document by docket ID number and other identifying information (subject heading, **Federal Register** date and page number).
2. Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.
3. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.
4. Describe any assumptions and provide any technical information and/or data that you used.
5. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.
6. Provide specific examples to illustrate your concerns and suggest alternatives.
7. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.
8. Make sure to submit your comments by the comment period deadline identified.

*C. How May I Participate in this Meeting?*

You may participate in this meeting by following the instructions in this unit. To ensure proper receipt by EPA, it is imperative that you identify docket ID number EPA-HQ-OPP-2013-0230 in the subject line on the first page of your request.

1. *Written comments.* The Agency encourages that written comments be submitted, using the instructions in **ADDRESSES**, no later than July 16, 2013, to provide FIFRA SAP the time necessary to consider and review the written comments. Written

comments are accepted until the date of the meeting, but anyone submitting written comments after July 16, 2013, should contact the DFO listed under **FOR FURTHER INFORMATION CONTACT**. Anyone submitting written comments at the meeting should bring 30 copies for distribution to FIFRA SAP.

2. *Oral comments.* The Agency encourages that each individual or group wishing to make brief oral comments to FIFRA SAP submit their request to the DFO listed under **FOR FURTHER INFORMATION CONTACT** no later than July 23, 2013, in order to be included on the meeting agenda. Requests to present oral comments will be accepted until the date of the meeting and, to the extent that time permits, the Chair of FIFRA SAP may permit the presentation of oral comments at the meeting by interested persons who have not previously requested time. The request should identify the name of the individual making the presentation, the organization (if any) the individual will represent, and any requirements for audiovisual equipment (e.g., overhead projector, 35 mm projector, chalkboard). Oral comments before FIFRA SAP are limited to approximately 5 minutes unless prior arrangements have been made. In addition, each speaker should bring 20 copies of his or her comments and presentation slides for distribution to the FIFRA SAP at the meeting.

3. *Seating at the meeting.* Seating at the meeting will be open and on a first-come basis.

4. *Request for nominations to serve as ad hoc members of FIFRA SAP for this meeting.* As part of a broader process for developing a pool of candidates for each meeting, FIFRA SAP staff routinely solicits the stakeholder community for nominations of prospective candidates for service as ad hoc members of FIFRA SAP. Any interested

person or organization may nominate qualified individuals to be considered as prospective candidates for a specific meeting. Individuals nominated for this meeting should have expertise in one or more of the following areas: Regulatory toxicology/weight-of-evidence risk assessment, ecotoxicology (fish and amphibian toxicology), comparative endocrinology, reproductive physiology, developmental biology/toxicology, thyroid physiology, *in vitro* models, toxicological pathology, amphibian histopathology, morphometrics, quantitative ecology/biostatistics, systems biology, and Bayesian statistics. Nominees should be scientists who have sufficient professional qualifications, including training and experience, to be capable of providing expert comments on the scientific issues for this meeting. Nominees should be identified by name, occupation, position, address, and telephone number. Nominations should be provided to the DFO listed under **FOR FURTHER INFORMATION CONTACT** on or before [*insert date 15 days from date of publication in the Federal Register*]. The Agency will consider all nominations of prospective candidates for this meeting that are received on or before this date. However, final selection of ad hoc members for this meeting is a discretionary function of the Agency.

The selection of scientists to serve on FIFRA SAP is based on the function of the panel and the expertise needed to address the Agency's charge to the panel. No interested scientists shall be ineligible to serve by reason of their membership on any other advisory committee to a Federal department or agency or their employment by a Federal department or agency, except the EPA. Other factors considered during the selection process include availability of the potential panel member to fully participate in the panel's reviews, absence of any conflicts of interest or appearance of lack of impartiality,

independence with respect to the matters under review, and lack of bias. Although financial conflicts of interest, the appearance of lack of impartiality, lack of independence, and bias may result in disqualification, the absence of such concerns does not assure that a candidate will be selected to serve on FIFRA SAP. Numerous qualified candidates are identified for each Panel. Therefore, selection decisions involve carefully weighing a number of factors including the candidates' areas of expertise and professional qualifications and achieving an overall balance of different scientific perspectives on the Panel. In order to have the collective breadth of experience needed to address the Agency's charge for this meeting, the Agency anticipates selecting approximately 15 ad hoc scientists.

FIFRA SAP members are subject to the provisions of 5 CFR part 2634, Executive Branch Financial Disclosure, as supplemented by the EPA in 5 CFR part 6401. In anticipation of this requirement, prospective candidates for service on the FIFRA SAP will be asked to submit confidential financial information which shall fully disclose, among other financial interests, the candidate's employment, stocks and bonds, and where applicable, sources of research support. The EPA will evaluate the candidates financial disclosure form to assess whether there are financial conflicts of interest, appearance of a lack of impartiality or any prior involvement with the development of the documents under consideration (including previous scientific peer review) before the candidate is considered further for service on FIFRA SAP. Those who are selected from the pool of prospective candidates will be asked to attend the public meetings and to participate in the discussion of key issues and assumptions at these meetings. In addition, they will be asked to review and to help finalize the meeting minutes. The list of FIFRA SAP

members participating at this meeting will be posted on the FIFRA SAP website at <http://www.epa.gov/scipoly/sap> or may be obtained from the OPP Docket at <http://www.regulations.gov>.

## **II. Background**

### *A. Purpose of FIFRA SAP*

FIFRA SAP serves as the primary scientific peer review mechanism of EPA's Office of Chemical Safety and Pollution Prevention (OCSPP) and is structured to provide scientific advice, information, and recommendations to the EPA Administrator on pesticides and pesticide-related issues as to the impact of regulatory actions on health and the environment. FIFRA SAP is a Federal advisory committee established in 1975 under FIFRA that operates in accordance with requirements of the Federal Advisory Committee Act. FIFRA SAP is composed of a permanent panel consisting of seven members who are appointed by the EPA Administrator from nominees provided by the National Institutes of Health and the National Science Foundation. FIFRA established a Science Review Board consisting of at least 60 scientists who are available to the FIFRA SAP on an ad hoc basis to assist in reviews conducted by the FIFRA SAP. As a peer review mechanism, FIFRA SAP provides comments, evaluations and recommendations to improve the effectiveness and quality of analyses made by Agency scientists. Members of FIFRA SAP are scientists who have sufficient professional qualifications, including training and experience, to provide expert advice and recommendation to the Agency.

### *B. Public Meeting*

EPA developed the Endocrine Disruptor Screening Program (EDSP) in response to FFDCA section 408(p) which requires EPA to "develop a screening program, using



appropriate validated test systems and other scientifically relevant information, to determine whether certain substances may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or such other endocrine effect as the Administrator may designate.” 21 U.S.C. 346a(p)(1). In addition, the provision in section 1457 of the Safe Drinking Water Act (SDWA) provides that “the Administrator may provide for testing under the screening program ... any other substance that may be found in sources of drinking water if the Administrator determines that a substantial population may be exposed to such substance.” 42 U.S.C. 300j-17.

Based on recommendations from the Endocrine Disrupter Screening and Testing Advisory Committee (EDSTAC) and, pursuant to the EPA Administrator’s discretionary authority, the EPA expanded the program to encompass the estrogen, androgen, and thyroid (E, A, and T) hormonal pathways of the endocrine system and human and ecological effects. Subsequent to review by a joint committee of the EPA’s Science Advisory Board (SAB) and the FIFRA SAP, the EDSP embarked on a validation process as mandated to evaluate the relevance and reliability of Tier 1 screening and Tier 2 test methods. As recommended by a FIFRA SAP, the current EDSP Tier 1 screening battery consists of both *in vitro* and *in vivo* assays that provide redundancy within a particular mode or pathway of action and complementary endocrine specific-endpoints sensitive enough to detect effects on E, A, and T signaling through different routes of exposure and across multiple life-stages and taxa. The degree of redundancy and complementary assays/endpoints are intended to provide corroborating information to support an evaluation of the Tier 1 screening results.

EPA issued the first test orders of the EDSP Tier 1 screening on 67 chemicals (List 1 chemicals) between October 29, 2009, and February 26, 2010 (<http://www.epa.gov/endo>). As a result of these test orders, EDSP Tier 1 data were submitted on 50 pesticide active ingredients and 2 pesticide inert ingredients. For some test orders, EPA accepted “other scientifically relevant information” (OSRI) in lieu of specific study data (<http://www.epa.gov/endo>).

In May 2013, the Agency will be holding a FIFRA SAP meeting to obtain input to ensure that individual assays and the overall battery performed as anticipated toward understanding whether a chemical is impacting E, A, and T pathways. A subset of the List 1 chemicals will be presented to the Panel to evaluate whether each assay can be consistently executed based on the performance criteria and to discuss any issues associated with interpretation of the responses within each assay as well as the anticipated complementary relationships both within and across the assays. The advice and recommendations of the Panel from the May FIFRA SAP will be critical in how the Agency conducts its weight-of-evidence (WoE) evaluation of the Tier 1 screening results, which is the topic of this FIFRA SAP.

The EPA issued its WoE guidance document in 2011 for evaluating the results of EDSP Tier 1 screening to identify the need for Tier 2 testing. That document can be found at <http://www.regulations.gov> (Docket ID number EPA-HQ-OPPT-2010-0877). Briefly, that document presents a hypothesis-based approach that begins with an evaluation of each study's quality and relevance in addressing the questions for the chemical of interest, and guidance on how to assemble and integrate all lines of evidence (EDSP Tier 1 assays and OSRI, including peer reviewed studies) for that chemical. Thus,

Tier 1 screening is combined with other relevant evidence (e.g., 40 CFR part 158 guideline studies) using a WoE analysis intended to determine whether or not a test chemical requires more comprehensive Tier 2 testing or a more targeted and tailored approach.

The Agency will present case studies based on a subset of List 1 chemicals for the Tier 1 test orders to illustrate the decision logic for applying EPA's EDSP WoE guidance (<http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPPT-2010-0877-0021>) in interpreting Tier 1 screening results and OSRI. The FIFRA SAP will be asked to comment on interpretative issues that arise during this WoE approach as well as the decision logic that guides the determination of whether higher level testing is needed.

#### *C. FIFRA SAP Documents and Meeting Minutes*

EPA's background paper, related supporting materials, charge/questions to FIFRA SAP, FIFRA SAP composition (i.e., members and ad hoc members for this meeting), and the meeting agenda will be available by early July. In addition, the Agency may provide additional background documents as the materials become available. You may obtain electronic copies of these documents, and certain other related documents that might be available electronically, at <http://www.regulations.gov> and the FIFRA SAP website at <http://www.epa.gov/scipoly/sap>.

FIFRA SAP will prepare meeting minutes summarizing its recommendations to the Agency approximately 90 days after the meeting. The meeting minutes will be posted on the FIFRA SAP website or may be obtained from the OPP Docket at <http://www.regulations.gov>.

**List of Subjects**

Environmental protection, Pesticides and pests.

Dated: April 9, 2013.

Steven M. Knott,

*Acting Director, Office of Science Coordination and Policy.*

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